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SEP 2 1 2007

medix i.c.s.a.

Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the Medix, NATAL CARE ST-MX/LX/BX incubator.

Company making the submission:

	This summary is submitted by:	**or**	Correspondent/US Agent:
Name Address	Medix i.c.s.a Calle 89 Jose Arias 293 (B1672ACA) Villa Lynch San Martin Buenos Aires Argentina		Delphi Consulting Group 11874 South Evelyn Circle Houston, Texas 77071-3404 USA
Telephone Fax Toll Free Contact E-mail	(54-11) 4754-5555 (54-11) 4754-1713 Juan Carlos Guerra jcguerra@medix.com.ar		(832) 285-9423 (832) 615-3550 (888) 216-6521 J. Harvey Knauss Harvey@delphiconsulting.com

1. **Device Name:**

Trade/Proprietary Name:	NATAL CARE ST-MX/LX/BX incubator
Common/Usual Name:	Neonatal Incubator
Classification Name:	Incubator, Neonatal, 21 CFR 880.5400

2. **Predicate Devices:**

The NATAL CARE ST-MX/LX/BX incubator is substantially equivalent to other neonatal incubators on the market such as: Medix PC-305, K920049, Medix i.c.s.a. and Isolette Infant Incubator, Model C2HS, Hill-Rom Air Shields, K001242.

3. **Intended Use Statement:**

Indications for Use: The Medix Natal Care ST-MX/LX/BX Intensive Care Incubator provides a controlled thermal environment for neonates who are unable to provide their own thermoregulation. The Medix Natal Care ST-MX/LX/BX Intensive Care Incubator can be used in two operating modes: Air Control Mode and Skin Control Mode with two probes that can be used with twins or for a follow up of central/peripheral temperature variations in a patient as a tool for the early detection of thermal stress-effect on the newborn.

4. **Description of Device:**

The NATAL CARE ST-MX/LX/BX incubator is a new updated line of intensive care incubators with skin and air microprocessor temperature control, incorporating the latest technical and design advances for neonatal care.

The distinctive features of an intensive care incubator are offered; together with large displays showing skin and air temperature, with their respective control temperatures. A graphic display (electroluminescent or LCD) allows the selection of a conflagration options menu, and checks modular accessories that are optionally incorporated (pulse oximetry, humidity servo control, oxygen servo control, weighing scales).

NATAL CARE ST-MX/LX/BX incubator is comprised of three main elements: the clear hood, shell and stand. Together they measure H 53 in X W 41.3 in X D 23.5 in.

Two skin temperature probes are incorporated, allowing its use with twins or for a follow up of central/peripheral temperature variations in a patient as a tool for the early detection of thermal stress- effect on the newborn.

Basic Models:

NATAL CARE ST-BX	INTENSIVE CARE UNIT INCUBATOR includes a mobile panel with displays for Air and Skin temperature, alarm indicators, Trendelemburg and Flowler continuous movement, double wall, 4 access doors with 180° swinging (two therapy and two lateral auxiliary ones), 4 oval hand ports, tow on each therapy door and one iris diaphragm port on one of the auxiliary doors, 8 IV ports, X-Ray tray. Additional accessories may be added.
NATAL CARE ST-LX	INTENSIVE CARE UNIT INCUBATOR includes a mobile panel with a LCD liquid crystal graphic display. Air and Skin temperature, alarms, curves, comfort zone, patient identification, electric Trendelemburg and Fowler, double wall with 180° swinging (two therapy and two lateral auxiliary ones), 4 oval hand ports, tow on each therapy door and one iris diaphragm port on one of the auxiliary doors, 8 IV ports, X-Ray tray. Additional accessories may be added.
NATAL CARE ST-MX	INTENSIVE CARE UNIT INCUBATOR includes a mobile panel with an electroluminescent display. Air and Skin temperature, alarms, curves, comfort zone, patient identification, electric Trendelemburg and Fowler, double wall with 180° swinging (two therapy and two lateral auxiliary ones), 4 oval hand ports, tow on each therapy door and one iris diaphragm port on one of the auxiliary doors, 8 IV ports, X-Ray tray. Additional accessories may be added.

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5. **Summary of the technological characteristics of the device compared to predicate devices:**

The modifications from the Medix PC-305 K920049 are:

- Redesign of system controller and display
- Redesign of airflow system, double walls
- Ability to use two body temperature sensors

The modifications from the Hill-Rom Air-Shields Isolette K001242 are: None.

Method of construction and materials are very similar. Method of operation and Indications for Use are the same as the predicate devices.

6. Testing:

Testing of the Medix NATAL CARE ST-MX/LX/BX incubator included functional performance and electrical safety testing as outlined in FDA Guidance Documents and regulations.

7. **Rx or OTC**

The Medix NATAL CARE ST-MX/LX/BX incubator is a Rx device. Prescription device per 21 CFR Subpart D.

8. **Conclusions:**

Based upon the testing and comparison to the predicate devices the Medix NATAL CARE ST-MX/LX/BX incubator has the same intended use, with similar technological characteristics. The system performs as intended and does not raise any new safety or effectiveness issues.

Medix i.c.s.a.

Eng. Juan Carlos Guerra
Vice President & CEO

Date: SHIPPED JAN 17 2007

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2007

Medix i.c.s.a
C/O Mr. James Harvey Knauss
Consultant
Delphi Consulting Group
11874 South Evelyn Circle
Houston, Texas 77071

Re: K070291
Trade/Device Name: MEDIX Natal Care Intensive Care Incubator, Models – Natal Care ST-MX/LX/BX
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FMZ
Dated: September 11, 2007
Received: September 12, 2007

Dear Mr. Knauss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

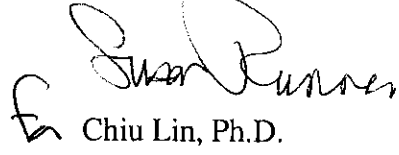
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K070291

Device Name: **MEDIX Natal Care Intensive Care Incubator, Models – Natal Care ST-MX/LX/BX**

Indications for Use: The Medix Natal Care ST-MX/LX/BX Intensive Care Incubator provides a controlled thermal environment for neonates who are unable to provide their own thermoregulation. The Medix Natal Care ST-MX/LX/BX Intensive Care Incubator can be used in two operating modes: Air Control Mode and Skin Control Mode with two probes that can be used with twins or for a follow up of central/peripheral temperature variations in a patient as a tool for the early detection of thermal stress-effect on the newborn.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K070291